SEP 19 2005

LANCER
ORTHODONTICS

SUMMARY

Submitter's name:	Lancer Orthodontics
Address:	253 Pawnee Street San Marcos, CA 92078
Phone:	760-744-5585
Fax number:	760-744-5842
Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821

Date the summary was prepared:	June 7, 2005
Name of the device:	O.A.S.I. System
Trade or proprietary name:	O.A.S.I. System
Common or usual name:	Mini Screws
Classification name:	Endosseous dental implant

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Dual Top Anchor Systems Screws by Jeil Medical Corporation, Reference number K033767.

Description of the device:

The O.A.S.I. System consists of self tapering titanium grade 5 (Ti6A14V) screws,

Indications:

This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.

Summary of the technological characteristics of our device compared to the predicate device:

The predicate Dual Top Anchor Systems Screws by Jeil Medical Corporation, K033767 and O.A.S.I. System microscrews were compared in the following areas and found to have similar technological characteristics and therefore to be equivalent.

Indications For Use
Target Population
Design
Materials
Sterility
Biocompatibility
Anatomical Sites
Where Used
Standards Met

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2005

Lancer Orthodontics, Inc.
C/O Ms. Grace Holland
Regulatory Specialists, Inc.
3722 Avenue Sausalito
Irvine, California 92606

Re: K051552
Trade/Device Name: O.A.S.I. System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE
Dated: August 24, 2005
Received: August 26, 2005

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

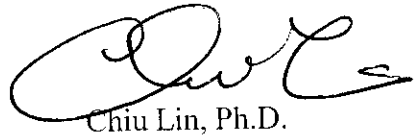
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051552

Device Name: O.A.S.I. System

Indications For Use:

This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single us only.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051552